

Docket no. JCT-002

Serial No. 10/084,523

**REMARKS**

Claims 1-22 remain pending in the present application. Claims 1-10 stand withdrawn from consideration pursuant to a restriction requirement issued by the Examiner. Claims 11-22 stand rejected on various grounds, discussed below.

Applicant submits that the amendment to claim 11 to indicate that each divided portion of the cord blood sample should contain stem cells, while not literally supported within the specification, is supported within the entirety of the specification and would have been understood to be contained therein by one skilled in the art.

**Rejection under 35 U.S.C. §112, second paragraph**

Claims 11-22 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicant traverses this basis for rejection and respectfully requests reconsideration and withdrawal thereof.

The Examiner objects to the claims as being inconsistent with the preamble of claim 11 and suggests that the method of claim 11, while characterized as a 'method for paying storage costs of blood', instead appears to drawn to a method for storing blood.

Applicant directs the Examiner's attention to the literal language of claim 11, which is directed to a "method of defraying the cost of a storage service for umbilical cord blood stem cells comprising dividing...[and] selling... a first portion of said...blood and using the proceeds...to defray the costs of storing a second portion of said...blood". The language and steps set forth in the body of claim 11 are clearly consistent with the preamble. The preamble is directed to a method of defraying costs of a storage service, and the body of claim 11, as well as the claims dependent thereon relate specific steps to achieve that goal. The steps of 'recovering, concentrating, diluting', etc. questioned by the Examiner at page 3 of the Office Action are merely optional additional steps which may

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be taken to enhance the value of the blood portions which are divided according to claim 11.

The Examiner additionally questions the clarity of the term "amplifying". Applicant directs the Examiner's attention to the specification at page 3, lines 34-36, wherein 'amplifying' is discussed. Applicant notes that the cited reference to Gonzales-Ryan similarly suggests 'cord blood expansion techniques' at page 110, first column.

As such, Applicant believes the nature of claims 11-22 to be entirely clear and unambiguous to those of skill in the art.

**Rejection under 35 U.S.C. §103(a) over Gonzalez-Ryan et al.**

**In view of Annas**

Claims 11-14 and 21-22 stand rejected under 35 U.S.C. §103(a) as being obvious over Gonzales-Ryan et al., in view of Annas. Applicant traverses this basis for rejection and respectfully requests reconsideration and withdrawal thereof.

Applicant agrees with the Examiner's general characterizations of the disclosures of the cited references, those disclosures being consistent with Applicant's discussion of the state of the art in the Background of the Invention section of the present specification at pages 1-2.

However, neither reference discloses or even suggests dividing of the collected sample of umbilical cord blood into at least two portions and selling or donating one portion and using the proceeds of the sale or donation to defray the cost of storing the other portion, as claimed herein.

The Examiner opines that it would have been obvious to the skilled artisan to pay for storing cord blood "in any way available, since it was known to be costly" (Office Action, page 4). Applicant respectfully submits that the Examiner's opinion fails to consider the 'dividing' step of the present claims, and that the Examiner's statement is clearly an impermissible hindsight reconstruction of the present invention, derived not from the cited prior art references, but from a reading of the present

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specification and claims. As such, the purported *prima facie* case of obviousness as to the present claims is improper.

Further, the Examiner is requested to consider the fact that Applicant's proposed method of defraying storage costs provides a solution to some of the ethical dilemmas raised by the cited references.

Annas discloses that one problem exists in that if storage fees are not paid, storage companies may deem the blood sample to become property of the company (page 1524, first column). However, according to the presently claimed method, the original owner of the blood sample would consent to division of the sample, with the proceeds of sale of one portion used to defray storage costs of the other. In this manner, storage costs will not go 'unpaid', and the remaining portion can be retained for the original owner without concern of ownership rights in the future.

Another dilemma which is solved by the presently claimed method is that presented a low-income 'donor' family, which might wish to have cord blood/stem cells preserved, but is financially unable to pay even the initial fees for such storage (Annas, page 1523, second column). By practicing the presently claimed invention, the low income 'donor' will have access to the expensive storage services for cord blood which they might not otherwise be able to afford.

Another dilemma which can be addressed by the presently claimed invention is that of providing access to cord blood stem cells for research. As stem cell research advances, it is likely that more legitimate therapeutic uses will be found for cord blood stem cells, which will invariably increase the demand for such materials in the health care field, but correspondingly reduce the supply available for future research. By practicing the present invention, it is likely that stem cells will be available for both therapeutic procedures and research.

The Examiner's attention is likewise directed to Gonzales-Ryan et al., wherein the authors also discuss such dilemmas (pages 109-110).

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Accordingly, Applicant believes that not only do the cited reference fail to teach each and every limitation of the present claims, especially the dividing step, but that the claimed invention can be used to solve some of the ethical dilemmas raised, but unsolved, by the cited references.

**Rejection under 35 U.S.C. §103(a) over Kline and/or Wolf, Jr.**

**In view of Annas**

Claims 11-14, 17, 18 and 21-22 stand rejected under 35 U.S.C. §103(a) as being obvious over Kline and/or Wolf, Jr., in view of Annas. Applicant traverses this basis for rejection and respectfully requests reconsideration and withdrawal thereof.

Applicant again essentially agrees with the Examiner's characterization of the cited references, but disagrees with the Examiner's conclusion as to the obviousness of the present claims in view of the references.

As recognized by the Examiner at the bottom of page 5 of the outstanding Office Action, none of the references disclose or suggest the 'method of payment' as claimed. That is, none of the references discloses or suggests division of a cord blood sample into different portions, each of which contains stem cells, and selling or donating one portion to defray the costs of storage of the other portion.

The Examiner again suggests that such a step would have been obvious to the skilled artisan, who would have been motivated 'to pay for storing cord blood in any way available...' (Office Action, top of page 6). Again, Applicant asserts that the Examiner's proposed motivation/solution is impermissibly derived from a reading of the present specification, and not from the prior art. Withdrawal of the rejection is requested on this basis alone, as the purported *prima facie* case of obviousness is improperly derived.

The Examiner is also requested to again consider the unexpected advantages which can be obtained by the present claims in solving the

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dilemmas presented by the prior art references, as discussed more fully above. Withdrawal of the rejection is requested on this basis.

**Rejection under 35 U.S.C. §103(a) over Boyse**

**In view of Annas**

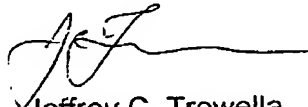
Claims 11-22 stand rejected under 35 U.S.C. §103(a) as being obvious over Boyse in view of Annas. Applicant traverses this basis for rejection and respectfully requests reconsideration and withdrawal thereof.

Applicant again essentially agrees with the Examiner's characterization of the cited references, but disagrees with the Examiner's conclusion as to the obviousness of the present claims in view of the references.

Once again, the cited references essentially disclose the state of the art, but fail to disclose or suggest the particular steps of dividing the cord blood into portions, each portion containing stem cells, and selling or donating one portion to defray the cost of storing the other portion. Likewise, Applicant respectfully suggests that the Examiner's opinion as to the obviousness of the present claim steps is impermissibly derived from a reading of the present specification, and finds no basis for support in the prior art.

Withdrawal of the rejections and allowance of the claims is requested.

Respectfully submitted,



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